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UNCLAS OTTAWA 001528

SIPDIS

SENSITIVE

DEPT FOR WHA/CAN (NORMAN)  
DEPT PASS TO USTR SCHANDLER, STROJE AND SBOMER  
USDA FOR FAS, INTERNATIONAL TRADE POLICY (SHEIKH, SIMMONS)  
COMMERCE FOR CBUSQUETS AND GWORD

E.O. 12958: N/A

TAGS: [ETRD](#) [EAGR](#) [CA](#)

SUBJECT: CEREAL FORTIFICATION - CANADA DEFERS AUTHORIZATION  
FOR U.S. NUTRIENT LEVELS

REF: 2002 OTTAWA 3225

This Cable is Sensitive but Unclassified; please handle accordingly.

1. (SBU) Summary - Health Canada has once again deferred making a final decision on General Mill's August 2001 application for temporary marketing authority to sell breakfast cereals with U.S. vitamin fortification levels in Canada. After their own analysis indicated that high levels of folic acid could mask a B-12 vitamin deficiency in children, Health Canada decided to wait for the results of an Institute of Medicine Study on the tolerable upper levels of nutrient intake before making a final judgment on General Mill's application. This will delay a decision on General Mill's submission until fall 2003, at the earliest. End Summary.

2. (U) Due to regulatory differences, American manufacturers must currently do separate production runs for the Canadian and U.S. markets in order to comply with different limits of vitamin and micro-nutrient fortification in each country. Both Health Canada and USG agencies are sponsoring a long-term study of Dietary Reference Intakes by the U.S. Institute of Medicine (IOM). When all phases of the study are completed in 2004, it will provide a common baseline for each country to review nutrient levels and harmonize nutritional standards. The IOM study is one element of an ongoing GOC review of Canada's food fortification policy.

3. (SBU) In August 2001, General Mills applied to Health Canada for a Temporary Marketing Authorization Letter (TMAL) to allow sales of their 19-product range of breakfast cereals in Canada at U.S. fortification levels. The TMAL would provide General Mills with immediate, but short-term regulatory relief to sell cereals fortified at U.S. levels while the IOM study and Canada's fortification policy are completed. TMALs are used to permit temporary marketing authorization when the benefits of a product are clear but the potential risks are still under study. TMALs have been granted by Health Canada for numerous products including calcium-enhanced orange juice and Omega-3 eggs. General Mills provided all the information requested by Health Canada, and even voluntarily changed fortification levels on zinc to Canadian standards. Well into the review process Health Canada raised additional concerns about the levels of folic acid and requested further studies. General Mills supplied additional data on folic acid in February 2003. As of mid-May, General Mills had heard nothing from Health Canada and asked the Embassy to intervene, which we did.

4. (SBU) On May 28, Health Canada Deputy Minister Ian Green informed the DCM and General Mills representatives of the results of their analysis of General Mill's data on folic acid. The Health Canada panel which reviewed the data is concerned that the levels of folic acid permitted under U.S. regulations could mask a vitamin B-12 deficiency in children. Green noted that studies on the upper levels of intake from other countries, including one from the United Kingdom, have raised similar concerns. Health Canada has decided to put off a final decision on General Mill's TMAL until after the publication of an IOM study on the upper reference levels of nutrients, which is due to be completed by September 30, 2003. This study is part of the larger IOM review of dietary reference intakes. Green promised to provide General Mills and the Embassy with a copy of the panel's report.

5. (SBU) Comment - We have been extremely frustrated by Health Canada's lack of transparency throughout the TMAL review process. Our numerous efforts to seek clarification from Health Canada on both the process and timing of their review have been regularly ignored or belatedly answered with bureaucratic doublespeak. General Mills has complained that Health Canada has repeatedly raised the bar as to what is required for approval of the TMAL. The current delay pending final results of the IOM study would appear to run counter to both the letter and spirit of the TMAL process. In our conversation with Green we stressed the importance of

ensuring that Health Canada takes a final decision on the  
TMAL shortly after the release of the IOM report.  
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